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10/516,404	11/30/2004	Wolfgang Demmer	3568.0100	2829

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Chernoff Vilhauer
McClung & Stenzel
1600 Ods Tower
601SW Second Avenue
Portland, OR 97204-3157

EXAMINER

UNDERDAHL, THANE E

ART UNIT	PAPER NUMBER
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1651

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/516,404	Applicant(s) DEMME ET AL.	
	Examiner THANE UNDERDAHL	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) 3-7,9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2, 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Applicant's reply received 11/15/07. Claims 1-7, 9, 10 and 12-14 are pending. Claims 3-7, 9, 10 are withdrawn. Claims 8 and 11 are cancelled. Claims 1-7, 9, 10, 12-14 have been amended. No claims are new.

Response to Applicant's Arguments— 35 U.S.C § 112

In the response submitted by the Applicant the 35 U.S.C § 112 rejection of claims 12-14 is withdrawn in light of the Applicant's amendment.

Response to Applicant's Arguments— 35 U.S.C § 102

In the response submitted by the Applicant, the 35 U.S.C § 102 (b) (c) rejection of remaining claims 1, 2, 13 over Klein et al. (U.S. Patent # 5766908) were considered but not found persuasive. Furthermore the rejection extends to newly amended claim 12.

The Applicant argues that the Examiner has improperly applied Klein et al. to the current claims. In particular the Applicant argues that there is a subtle difference between Klein et al. and the current invention. This subtle difference being:

"Klein does not react his microporous membrane with a functional group such as an aldehyde to bind the affinity ligand to the membrane. Instead, Klein begins with a microporous membrane that has free reactive or functional groups for coupling the affinity ligand" (Applicant's Response, pg 5, last paragraph).

While the Examiner appreciates having these subtleties pointed out in such a distinct and direct fashion the Examples provided by Klein et al. do not agree with the

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Applicant's assertions. In particular in Example 1, Klein et al. teach that the cellulose can first be "activated" with a bifunctional linking agent to provide "a leash from the fiber for the attachment of the Neutrased enzyme" (col 10, lines 46-56). Example 1 teaches a procedure where the cellulose is derivatized by the bifunctional linking agent (col 10, lines 60-65) and then the enzyme was attached to the membrane via the linking agent (col 11, lines 10). Example 2 teaches a similar scenario where the cellulose is first modified with a bifunctional linking agent and then the enzyme is attached. Therefore it is clear from the examples that Klein et al. indeed does teach that the cellulose is modified with the functional groups of the linking agent and then the enzyme is added.

Furthermore since the claim has been amended to a product and not to a method it is now considered a product-by-process claim. Product by Process claims are not limited by the manipulations of the recited steps, only the structure implied by the steps (M.P.E.P. § 2113). As such, these methods of preparation while imparting a functional relationship to the membrane, it is the final structure of the membrane that carries the patentable weight and not the steps used to create it. Therefore the rejection stands and is repeated below with modifications to address the claim amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 12 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al. (U.S. Patent # 5766908).

These claims are drawn to a membrane with affinity for biomolecules made by the following steps:

- (a) providing a microporous membrane;
- (b) reacting said membrane of step (a) with a reagent containing a functional group to form a functionalized membrane containing reactive functional groups on the surfaces thereof;
- (c) contacting said functionalized membrane of step (b) with a solution containing an affinity ligand to couple said ligand to said functional group to form a biologically active membrane;
- (d) washing said biologically active membrane with a washing solution containing a volatile organic compound that is miscible with said washing solution; and
- (e) drying said biologically active membrane.

The functional group of step b can be an aldehyde. Claim 12 limits that the membrane is impregnated with glycerine. Claim 13 limits that this membrane product is placed within a filtration housing with a fluid inlet and outlet.

Klein et al. teach a microporous membrane made from hydrogel or cellulose fiber that is surface modified with an affinity ligand such as a protein, antibody or cell receptor (see Abstract and Examples 1 and 2). The microporous membrane is reacted with a functional group such as an aldehyde (col 9, lines 50-60) to bind the affinity ligand to the membrane. The membrane is washed with many water miscible and volatile solvents such as acetone (Example 2) and mixtures of water and N-methylpyrrolidone (Example 6) and dried. The membrane is also soaked with a solution of water/isopropanol/glycerol (Example 5, col 16, lines 1-5). Glycerol is synonymous with glycerine or glycerin. The membrane is then centrifuged to remove only the excess

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glycerol after the membrane is inherently impregnated with said glycerol (col 16, lines 1-5) via this process. The membrane is formed into a column that has a defined flow rate which inherently must have an inlet and outlet (Col 12, lines 20-35).

Therefore the reference anticipates claims 1, 2, 12 and 13.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 1, 2, 12-14 over Klein et al. (U.S. Patent # 5766908) were considered but not found persuasive.

Concerning the remaining 35 U.S.C § 103 (a) rejections in the Office Action the Applicant argues that since the new limitations/amendments of the parent claim 1 overcome the teachings of Klein et al. that they in turn overcome the remaining rejections that use these references. However as detailed above the Examiner disagrees and believes that the rejection over Klein et al. is proper and in the absence of arguments to the contrary these rejections stand for the amended claims and are repeated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 12-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. as applied above to claims 1, 2, 12 and 13 and in further view of the rational outlined below.

The description and rejection of claims 1, 2, 12 and 13 are listed in the 35 U.S.C § 102(b) rejection above. Claim 14 limits that the filtration housing from claim 13 contains three membrane products.

While Klein et al. does teach a filtration housing that contains one membrane product, they do not teach three membrane products. However M.P.E.P. § 2144.06 states

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more membrane products that serve the same purpose to the filtration housing.

Also M.P.E.P. § 2144.04 VI B state:

"that mere duplication of parts has no patentable significance unless a new and unexpected result is produced"

Therefore simply adding more membrane products that serve the same purpose to the filter housing is obvious in the absence of evidence to the contrary.

Therefore the references listed above renders obvious claims 1, 2 and 12-14.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

Thane Underdahl
Art Unit 1651

Leon B. Lankford Jr
Primary Examiner
Art Unit 1651